

### **REMARKS/ARGUMENTS**

In response to the Office Action dated September 21, 2005, Applicants respectfully request the Office to enter the following amendments and consider the following remarks. By this response, Applicants amend claim 1, withdraw claims 21 and 22 without prejudice or disclaimer, and add new claims 23 and 24. After entry of this paper, claims 1-18 and 23-24 will be subject to examination in this application.

In the Office Action, the Examiner (i) issued a restriction requirement concerning claims 21-22; (ii) rejected claims 1, 10-12 and 14-18 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,762,049 to Zou *et al.* ("Zou"); (iii) rejected claims 1, 10-12, and 14-18 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,379,929 to Burns *et al.* ("Burns"); (iv) rejected claims 2, 6-9, and 13 under 35 U.S.C. § 103(a) as being unpatentable over Zou in view of U.S. Patent No. 6,203,683 to Austin *et al.* ("Austin"); (v) rejected claims 3-5 under 35 U.S.C. § 103(a) as being unpatentable over Zou in view of Austin as applied to claim 2, and further in view of U.S. Patent No. 5,599,502 to Miyazaki *et al.* ("Miyazaki"); (vi) rejected claims 2-9 and 13 under 35 U.S.C. § 103(a) as being unpatentable over Burns in view of Austin; and (vii) rejected claims 3-5 under 35 U.S.C. § 103(a) as being unpatentable over Burns in view of Austin, as applied to claim 2, and further in view of Miyazaki.

#### **Election/Restriction**

Although Applicants respectfully disagree with the restriction, Applicants withdraw claims 21 and 22 in the interest of expediting prosecution and avoiding additional cost. Applicants respectfully reserve the right to request rejoinder if and when the appropriate circumstances arise.

#### **REJECTION BASED ON CITED ART**

Applicants respectfully disagree with these rejections, but nevertheless amend independent claim 1 in the interest of expediting prosecution and avoiding additional cost. Claim 1 now recites the use of "an optical temperature monitor, not

in contact with the cartridge and disposed adjacent to a portion of the cartridge surrounding the temperature controlled zones, that monitors reactant temperature by measuring electromagnetic radiation.” None of the prior art references cited by the Examiner teach or suggest at least this recitation. All other pending claims depend from claim 1 and include this new recitation. Thus, Applicants traverse the rejections of pending claims 1-18.

### 35 U.S.C. § 102(e) Rejections

Claims 1, 10-12 and 14-18 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Zou. See Office Action, page 3, section I. Claims 1, 10-12, and 14-18 also stand rejected under 35 U.S.C. § 102(e) as being anticipated by Burns. See Office Action, page 5, Section II. To establish anticipation under § 102, each and every element of the claim must be described, either explicitly or inherently, in a single prior art reference. See MPEP § 2131. In the present application, neither Zou nor Burns discloses every element in Applicants’ claims. Specifically, these references fail to disclose or suggest the use of “an optical temperature monitor, not in contact with the cartridge and disposed adjacent to a portion of the cartridge surrounding the temperature controlled zones, that monitors reactant temperature by measuring electromagnetic radiation” as recited in Applicants’ amended claim 1.

#### Zou et al.

Zou teaches “a thermal cycler for multi-chamber independent thermal control, using low-cost reusable or disposable miniaturized reaction chips.” Zou, col. 2, lines 30-32. It also discloses “a process to manufacture said thermal cycler.” Zou, col. 2, lines 33-34. In this system, “high thermal conductance temperature balancing blocks 1 . . . are attached to a low thermal conductance substrate 2 such as a printed circuit board in an array format for multiple chambers 6.” Zou, col. 2, lines 62-67. “At least one chamber 6 is put on top of each block 1. Heaters and temperature sensors can be on top or bottom of the block 1.” Zou, col. 3, lines 16-19. Thus, the temperature sensor is located on the block, which is adjoining the temperature controlled chamber. Further, the temperature sensors provide the temperature of the blocks, not of the reactant within the chamber. Zou, col. 5, lines

33-34. In addition, nowhere does Zou disclose the use of optical sensors in particular. As a result, Zou fails to teach or suggest the use of "an optical temperature monitor, not in contact with the cartridge and disposed adjacent to a portion of the cartridge surrounding the temperature controlled zones, that monitors reactant temperature by measuring electromagnetic radiation" as recited in Applicants' amended claim 1.

For at least the foregoing reasons, Zou fails to anticipate Applicants' amended claim 1. Further, claims 10-12 and 14-18 depend from and include all limitations of amended claim 1, and are thus allowable for at least the same reasons. Therefore, Applicants request that the rejection of these claims under 35 U.S.C. §102(e) be withdrawn.

Burns et al.

Claims 1, 10-12, and 14-18 stand rejected as anticipated by Burns. Burns, however, fails to teach or suggest all elements of Applicants' claim 1. Burns teaches a system and method "for isothermal amplification of nucleic acids in a microfabricated substrate." Burns, Abstract. As part of this system, Burns discloses that "means for isothermally regulating the reaction chamber may include, but are not limited to, resistors in contact with or in proximity to the reaction chamber, temperature detectors, resistive temperature detectors, dielectric sensors, or diodes and/or circuitry for temperature control." Burns, col. 6, lines 7-11. In fabricating the device, according to Burns, "platinum ('PT') is electron beam deposited. . . . This platinum will be used as the resistive thermal detector." Burns, col. 28, lines 55-60. Resistive elements measure temperature by correlating the resistance in the material to a temperature. To monitor the temperature in a region, resistive temperature elements must be located within that region. Thus, resistive temperature elements located adjacent to the temperature controlled region will measure the temperature at that location, not the temperature of the reactant within the temperature controlled region. In addition to the resistive temperature element, Burns also teaches the use of a radiation detector "fashioned directly into the silicon substrate underneath the channel." Burns, col. 32, lines 5-8. This "integral radiation

detector," however, detects "individual decay events from . . . DNA", not temperature. Burns, col. 31, lines 13-14. As a result, Burns fails to teach or suggest the use of "an optical temperature monitor, not in contact with the cartridge and disposed adjacent to a portion of the cartridge surrounding the temperature controlled zones, that monitors reactant temperature by measuring electromagnetic radiation" as recited in Applicants' amended claim 1.

For at least the foregoing reasons, Burns fails to anticipate Applicants' amended claim 1. Further, claims 10-12 and 14-18 depend from and include all limitations of amended claim 1, and are thus allowable for at least the same reasons. Therefore, Applicants request that the rejection of these claims under 35 U.S.C. §102(e) be withdrawn.

#### 35 U.S.C. §103(a) Rejections

In the present Office Action, claims 2, 6-9, and 13 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Zou in view of Austin; claims 3-5, as unpatentable over Zou in view of Austin and in further view of Miyazaki; claims 2-9 and 13, over Burn in view of Austin; and claims 3-5, over Burns in view of Austin and in further view of Miyazaki. See Office Action pages 8-11. In a § 103(a) rejection, the Examiner must establish the three elements of a *prima facie* case of obviousness. MPEP § 2142. First, the Examiner must show that the prior art references teach all elements of the claims. Second, the Examiner must show that the prior art provides the reason or motivation to make the claimed combination. The mere fact that references can be combined does not create a *prima facie* case of obviousness. Moreover, the motivation to combine cannot come from the applicant's own disclosure but must come from the prior art itself. Additionally, no motivation to combine references exists where doing so would render one of the prior art references unsatisfactory for its intended purpose. Third, the Examiner must prove that there is a reasonable expectation of success in combining the prior art references.

In the present application, the cited references, either alone or taken together,

fail to teach all of the elements of the claims. Zou and Burns, as discussed above, fail to disclose the use of "an optical temperature monitor, not in contact with the cartridge and disposed adjacent to a portion of the cartridge surrounding the temperature controlled zones, that monitors reactant temperature by measuring electromagnetic radiation" as recited in Applicants' amended claim 1. Neither Austin nor Miyazaki cures this deficiency.

Zou et al. in view of Austin et al.

Claims 2, 6-9, and 13 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Zou in view of Austin. See Office Action page 8, paragraph 1. As discussed above, Zou fails to teach the use of "an optical temperature monitor, not in contact with the cartridge and disposed adjacent to a portion of the cartridge surrounding the temperature controlled zones, that monitors reactant temperature by measuring electromagnetic radiation" as recited in Applicants' claim 1. Austin fails to cure this deficiency.

Austin teaches a system relating to "a microfluidic device for trapping nucleic acids on an electrode by dielectrophoresis, thermocycling them on the electrode, and then releasing them . . . for analysis." Austin col. 2, lines 63-67. According to Austin et al.:

The inventive device differs from the prior art in modifications which were not previously known or suggested, such as . . .  
using the trapping electrode as a heater and in-situ temperature sensor.

Austin, col. 3, lines 38-42. Accordingly, Austin discloses "an intrinsic . . . heat source and temperature measurement" in which the temperature measurement device is located on the heat source that traps the nucleic acids to be heated. Austin, col. 32-35. Thus, Austin fails to teach or suggest the use of "an optical temperature monitor, not in contact with the cartridge and disposed adjacent to a portion of the cartridge surrounding the temperature controlled zones, that monitors reactant temperature by measuring electromagnetic radiation" as recited in Applicants' amended claim 1. Claims 2, 6-9, and 13 depend from, and include all limitations of, amended claim 1. Thus, Applicants submit that claims 2, 6-9,

and 13 are patentable over Zou in view of Austin for at least the same reasons as claim 1. Accordingly, Applicants request that the instant rejection of these claims under 35 U.S.C. §103(a) be withdrawn and the claims allowed.

Zou et al. in view of Austin et al. in further view of Miyazaki et al.

Claims 3-5 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Zou in view of Austin in further view of Miyazaki. See Office Action page 9, paragraph 2. As discussed above, both Zou and Austin fail to teach the use of “an optical temperature monitor, not in contact with the cartridge and disposed adjacent to a portion of the cartridge surrounding the temperature controlled zones, that monitors reactant temperature by measuring electromagnetic radiation” as recited in Applicants’ amended claim 1. Miyazaki fails to cure this deficiency.

Miyazaki discloses a method and device for “feeding a slight quantity of liquid without any pulsating flow.” Miyazaki, col. 1, lines 62-63. According to Miyazaki:

[A] responsive element for effecting the measurement of the sample liquid is provided on the surface of the first base plate 51. Specifically, in order to optically detect the state of the sample liquid, a first light detecting element, a first optical filter having the wavelength selecting function, a second light detecting element and a second optical filter are formed on the base plate.”

Miyazaki, col. 8, lines 3-9.

Further, “a first base plate 51, a second base plate 52 and a third base plate 53 are joined together . . . . By the joining of these base plates, a space forming an accumulating portion 54 which is a reacting bath is formed in the cartridge.”

Miyazaki, col. 7, lines 34-40. Thus, the light detecting elements form part of the same structure that holds the fluid to be measured. Further, Miyazaki fails to disclose using the light detecting element to detect temperature. Accordingly, Miyazaki fails to teach or suggest the use of “an optical temperature monitor, not in contact with the cartridge and disposed adjacent to a portion of the cartridge surrounding the temperature controlled zones, that monitors reactant temperature by measuring electromagnetic radiation” as recited in Applicants’ amended claim 1. Claims 3-5 depend from, and include all limitations of, amended claim 1. Thus,

Applicants submit that claims 3-5 are patentable over Zou in view of Austin and in further view of Miyazaki for at least the same reasons as claim 1. Accordingly, Applicants request that the instant rejection of claims 3-5 under 35 U.S.C. §103(a) be withdrawn and the claims allowed.

Burns *et al.* in view of Austin *et al.*

Claims 2-9 and 13 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Burns in view of Austin. See Office Action page 9, paragraph 6. As discussed above, neither Burns nor Austin contains all limitations of Applicants' amended claim 1. Specifically, neither reference discloses the use of "an optical temperature monitor, not in contact with the cartridge and disposed adjacent to a portion of the cartridge surrounding the temperature controlled zones, that monitors reactant temperature by measuring electromagnetic radiation" as recited in Applicants' amended claim 1. Claims 2-9 and 13 depend from, and include all limitations of, Applicants' amended claim 1. Thus, Applicants submit that claims 2-9 and 13 are patentable over Burns *et al.* in view of Austin *et al.* for at least the same reasons as claim 1. Accordingly, Applicants request that the instant rejection of these claims under 35 U.S.C. §103(a) be withdrawn and the claims allowed.

Burns *et al.* in view of Austin *et al.* in further view of Miyazaki *et al.*

Claims 3-5 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Burns in view of Austin, as applied to claim 2, and further in view of Miyazaki. See Office Action page 11, paragraph 1. As discussed above, none of these references teaches all elements of claim 1. Specifically, these references fail to teach or suggest the use of "an optical temperature monitor, not in contact with the cartridge and disposed adjacent to a portion of the cartridge surrounding the temperature controlled zones, that monitors reactant temperature by measuring electromagnetic radiation" as recited in Applicants' amended claim 1. Claims 3-5 depend from, and include all limitations of amended claim 1. Thus, Applicants submit that claims 3-5 are patentable over Burns in view of Austin and in further view of Miyazaki for at least the same reasons as claim 1. Accordingly, Applicants request that the instant rejection of these claims under 35 U.S.C. §103(a) be

withdrawn and the claims allowed.

New claims:

Applicants respectfully submit that new Claims 23-24 do not raise new issues or present new matter, nor do they necessitate any additional search, because these claims relate to subject matter in existing dependent claims and/or from paragraph 0029. Thus, the elements and relationships recite subject matter already before the Office and no new matter or issues are presented by this response. The new claims, which are all dependent claims, are also allowable because they depend on allowable base Claim 1. New claims 23-24 are thus allowable for at least the same reasons set forth with respect to Claim 1. Accordingly, Applicants respectfully request allowance of new Claims 23-24.

CONCLUSION

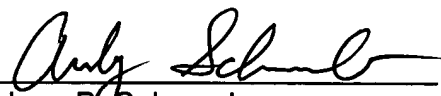
In view of the foregoing remarks, Applicants submit that this claimed invention is allowable over the references cited against this application. Applicants therefore request the entry of this Amendment, reconsideration and reexamination of the application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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